

(d) *Special considerations.* When labeled for the treatment of anaplasmosis or anthrax, labeling shall also bear the following: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(e) *Conditions of use*—(1) *Beef cattle, dairy cattle, and calves including preruminative (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of body weight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp., and anthrax caused by *Bacillus anthracis*.

(B) 5 mg/lb BW/day intramuscularly or intravenously for treatment of anaplasmosis caused by *Anaplasma marginale*, severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical, for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*, or where retreatment for anaplasmosis is impractical.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pink eye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*.

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL

intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter.

[45 FR 16479, Mar. 14, 1980, as amended at 46 FR 20160, Apr. 3, 1981; 46 FR 27913, May 22, 1981; 52 FR 19502, May 26, 1987; 60 FR 14218, Mar. 16, 1995; 60 FR 29755, June 6, 1995; 61 FR 31028, June 19, 1996; 61 FR 36291, July 10, 1996; 62 FR 13825, Mar. 24, 1997; 62 FR 27692, May 21, 1997; 63 FR 52158, Sept. 30, 1998; 64 FR 23187, Apr. 30, 1999; 64 FR 26670, May 17, 1999; 64 FR 42831, Aug. 6, 1999; 66 FR 13235, Mar. 5, 2001; 67 FR 12471, Mar. 19, 2002; 67 FR 47451, July 19, 2002; 67 FR 72366, 72367, Dec. 5, 2002; 67 FR 78357, Dec. 24, 2002; 68 FR 8153, Feb. 20, 2003; 68 FR 54806, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004; 69 FR 62406, Oct. 26, 2004]

§ 522.1660b Oxytetracycline injection, 300 milligram/milliliter.

(a) *Specifications.* Each milliliter (mL) of solution contains 300 milligrams (mg) oxytetracycline base.

(b) *Sponsor.* See No. 055529 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.500 of this chapter.

(d) *Special considerations.* When labeled for use as in paragraph (e)(1)(i)(D)

or (e)(1)(i)(E) of this section, labeling shall also bear the following: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”.

(e) *Conditions of use*—(1) *Beef cattle, nonlactating dairy cattle, and calves including preruminating (veal) calves*—(i) *Amounts and indications for use*—(A) 3 to 5 mg per pound of bodyweight (mg/lb BW) per day (/day) intramuscularly, subcutaneously, or intravenously for treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot-rot and diphtheria caused by *Fusobacterium necrophorum*, bacterial enteritis (scours) caused by *Escherichia coli*, wooden tongue caused by *Actinobacillus lignieresii*, leptospirosis caused by *Leptospira pomona*, wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(B) 5 mg/lb BW/day intramuscularly, subcutaneously, or intravenously for treatment of severe foot-rot, and advanced cases of other indicated diseases.

(C) 9 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(D) 9 to 13.6 mg/lb BW intramuscularly or subcutaneously as single dosage where retreatment of calves and yearlings for bacterial pneumonia is impractical or for treatment of infectious bovine keratoconjunctivitis (pinkeye) caused by *Moraxella bovis*.

(E) 13.6 mg/lb BW intramuscularly or subcutaneously as a single dosage for control of respiratory disease in cattle at high risk of developing BRD associated with *Mannheimia* (*Pasteurella*) *haemolytica*.

(ii) *Limitations*. Treatment should be continued 24 to 48 hours following remission of disease signs, however, not to exceed a total of four consecutive days. Do not inject more than 10 mL per site in adult cattle, reducing the volume according to age and body size to 1 to 2 mL in small calves. Exceeding the highest recommended level of drug/lb BW/day, administering more than

the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site may result in antibiotic residues beyond the withdrawal time. Rapid intravenous administration in cattle may result in animal collapse. Oxytetracycline should be administered intravenously slowly over a period of at least 5 minutes. Discontinue treatment at least 28 days prior to slaughter. Not for use in lactating dairy animals.

(2) *Swine*—(i) *Amounts and indications for use*—(A) Sows: 3 mg/lb BW intramuscularly once, approximately 8 hours before farrowing or immediately after completion of farrowing, as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *E. coli*.

(B) 3 to 5 mg/lb BW/day intramuscularly for treatment of bacterial enteritis (scours, colibacillosis) caused by *E. coli*, pneumonia caused by *Pasteurella multocida*, and leptospirosis caused by *Leptospira pomona*.

(C) 9 mg/lb BW as a single dosage where retreatment for pneumonia is impractical.

(ii) *Limitations*. Administer intramuscularly. Treatment should be continued 24 to 48 hours beyond remission of disease signs, however, not to exceed a total of 4 consecutive days. Exceeding the highest recommended level of drug/lb BW/day, administering more than the recommended number of treatments, and/or exceeding 5 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 28 days prior to slaughter.

[68 FR 54805, Sept. 19, 2003. Redesignated and amended at 69 FR 31879, June 8, 2004]

§ 522.1662 Oxytetracycline hydrochloride implantation or injectable dosage forms.

§ 522.1662a Oxytetracycline hydrochloride injection.

(a)(1) *Specifications*. The drug contains 50 milligrams of oxytetracycline hydrochloride in each milliliter of sterile solution.

(2) *Sponsor*. See No. 000010 in § 510.600(c) of this chapter.